**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF MISSOURI**
**EASTERN DIVISION**

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| DENISE NEELEY and HAROLD NEELEY, | ) | |
| Plaintiffs, | ) | No. 4:11-CV-325 JAR |
| v. | ) | |
| WOLTERS KLUWER HEALTH, INC., et al., | ) | |
| Defendants. | ) | |

**AMENDED MEMORANDUM AND ORDER**

This matter is before the court on Defendants Wolters Kluwer Health, Inc. and Wolters Kluwer United States, Inc.'s Motion to Dismiss (ECF No. 144), Barr Laboratories, Inc.; Barr Pharmaceuticals, LLC; and Watson Laboratories, Inc.'s Motion to Dismiss (ECF No. 146), Barr Laboratories, Inc.; Barr Pharmaceuticals, LLC; Watson Laboratories, Inc.; Wolters Kluwer Health, Inc.; and Wolters Kluwer United States, Inc.'s Motion to Dismiss Based On Insufficient Allegations (ECF No. 148), Defendant Watson Pharma, Inc.'s Notice of Joinder in Barr Laboratories, Inc.; Barr Pharmaceuticals, LLC; Watson Laboratories, Inc.; Wolters Kluwer Health, Inc.; and Wolters Kluwer United States, Inc.'s Motion to Dismiss Based On Insufficient Allegations (ECF No. 167), and Defendant Wyeth LLC, Wyeth Pharmaceuticals Inc., and Schwartz Pharma, Inc. n/k/a UCB, Inc.'s Motion for Summary Judgment (ECF No. 174). These matters are fully briefed and ready for disposition.

## BACKGROUND

In November 2006, Plaintiff Denise Neeley's (referred to herein as "Plaintiff" or "Ms. Neeley") physician prescribed her Reglan three times per day to treat gastroesophageal reflux disease (GERD). (Second Amended Complaint and Demand for Jury Trial ("Compl." or "Complaint"), ECF No. 122, ¶71). Reglan is sold as a generic drug as metoclopramide ("MCP"). Plaintiff admits that she ingested only the generic MCP. (ECF No. 164; Compl., ¶75) From approximately November 2006 through February 2008, Plaintiff ingested 10 mg of MCP approximately three times per day. (Compl., ¶72). Plaintiff also had been prescribed Reglan/MCP off and on for over a thirty-year period beginning in approximately 1987. On April 12, 2010, Plaintiff was diagnosed with tardive dyskinesia. (Compl., ¶¶79, 80).

On July 25, 2012, Plaintiffs Denise and Harold Neeley filed their Second Amended Complaint. Wyeth, LLC, Wyeth Pharmaceuticals, Inc., and Schwarz Pharma, Inc., n/k/a/ UCB, Inc., are referred to herein as the "Brand Defendants." (Compl., ¶37).[1] Barr Laboratories, Inc.; Barr Pharmaceuticals, LLC; and Watson Laboratories, Inc., and Watson Pharma, Inc. are referred to herein as the "Generic Defendants." (Compl., ¶38). Wolters Kluwer Health, Inc.; and Wolters Kluwer United States, Inc. are referred to herein as the "PEM Defendants." (Compl., ¶39).

## DISCUSSION

### I. Motions to Dismiss

#### A. Standard of Review

In ruling on a motion to dismiss, the Court must view the allegations in the Complaint liberally in the light most favorable to Plaintiff. Eckert v. Titan Tire Corp., 514 F.3d 801, 806

[1] Pursuant to this Court's October 9, 2012 Order, Defendant Alaven Pharmaceutical LLC was dismissed from this case without prejudice. (ECF No. 155).

(8th Cir. 2008)(citing Luney v. SGS Auto Servs., 432 F.3d 866, 867 (8th Cir. 2005)). Additionally, the Court "must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party." Coons v. Mineta, 410 F.3d 1036, 1039 (8th Cir. 2005) (citation omitted). To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007) (abrogating the "no set of facts" standard for Fed. R. Civ. P. 12(b)(6) found in Conley v. Gibson, 355 U.S. 41, 45–46 (1957)). While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555; Huang v. Gateway Hotel Holdings, 520 F. Supp. 2d 1137, 1140 (E.D. Mo. 2007).

**B. Generic Defendants**

**1. Hatch-Waxman Amendments and FDA Regulations**

The labeling of prescription drugs is governed by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §301, *et seq*. "A manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574, 180 L. Ed. 2d 580 (2011). In 1984, Congress amended the FDCA to allow generic drug manufacturers "to gain FDA approval simply by showing that its drug is equivalent to an already-approved brand-name drug, and that the safety and efficacy labeling proposed for its drug is the same as that approved for the brand-name drug." Id. These amendments, commonly referred to as the Hatch-Waxman Amendments,

allowed generic manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug. Id.

"To obtain approval for a generic drug, the manufacturer generally must show the generic drug is 'bioequivalent' to the brand name drug and has the same active ingredients, route of administration, dosage and strength." Bell v. Pfizer, Inc., 716 F.3d 1087, 1094 (8th Cir. 2013)(citing 21 U.S.C. §355(j)(2)(A)). A generic drug application must also 'show that the [safety and efficacy] labeling proposed ... is the same as the labeling approved for the [brand-name] drug.'" Mensing, 131 S. Ct. at 2574 (quoting § 355(j)(2)(A)(v))(alterations in Mensing). "[G]eneric drug manufacturers have an ongoing federal duty of 'sameness.'" Mensing, 131 S. Ct. at 2575. FDA regulations "allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." Mensing, 131 S. Ct. at 2575-76 (deferring to the FDA's interpretation of its CBE [changes-being effected process] and generic labeling regulations).

"The federal labeling regulations also apply to letters providing 'additional warnings to prescribing physicians and other healthcare professionals' (Dear Doctor letters), which must be 'consistent with and not contrary to [the drug's] approved … labeling.'" Mensing, 131 S.Ct. at 2576 (quoting 21 C.F.R. §201.100(d)(1))(alterations in Mensing). "A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling." Mensing, 131 S. Ct. at 2576. Likewise, "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" Mensing, 131 S. Ct. at 2576.

**2. Conflict of Laws**

The parties seem to agree that Kentucky law applies to their state law claims and, therefore, no conflict of law analysis is required. See, e.g., ECF No. 102, pp. 5, 14[2]; ECF No. 147, p. 33 (both applying Kentucky law).

**3. Discussion**

Plaintiffs allege claims against Generic Defendants for negligence, negligent misrepresentation and negligent supply of information for the guidance of others (Count II), breach of warranty (Counts IV), misrepresentation and fraud (Count V), strict product liability (Count VIII), violation of the Missouri Merchandising Practices Act ("MMPA") and/or Kentucky Consumer Protection Act ("KCPA") (Count IX), joint and several liability, enterprise liability, market share liability, concert of action liability (Count X), loss of consortium (Count XII), punitive damages (Count XIII), and Plaintiff's damages (Count XIV). Plaintiffs' claims against Generic Defendants arise primarily from their failure to update their warnings to comport with the brand name defendants' warnings. Specifically, Plaintiffs allege that "[b]y failing to update their drug information, including their labels, package inserts, drug databases and PEMs, distributed to doctors and patients alike, Defendants inaccurately warned of true risks of Reglan/MCP and misrepresented the safety of the drug for long-term usage." (Compl., ¶123). Plaintiffs contend that "Generic Defendants failed to update and/or revise their labels for their Reglan/MCP products with the 1985, 2004, and/or 2009 FDA-mandated label revisions, thereby failing to adequately warn of the true risks of the use of Reglan/MCP and misleading physicians, patients and the healthcare community to believe long term use of Reglan/MCP (longer than twelve weeks) was safe." (Compl., ¶284).

[2] In a separate brief, Plaintiffs contend that Kentucky law does not apply to their claims (ECF No. 158, p. 17 (referring the Court to ECF No. 102)), but this seems to contradict Plaintiffs' position in ECF No. 102.

Generic Defendants first contend that the case should be dismissed because the Court does not have jurisdiction over them. (ECF No. 147, p. 2). In addition, Generic Defendants contend that Plaintiffs' lawsuit should be dismissed because it is preempted by federal law. (Id.).

a. Personal Jurisdiction over Generic Defendants

Generic Defendants contend that this Court lacks either specific or general jurisdiction. None of the Generic Defendants have their principal place of business in Missouri, nor are they incorporated in Missouri. (ECF No. 147, p. 6). Generic Defendants assert that Plaintiffs are Kentucky residents and the events allegedly causing them injury have no connection to this forum. (ECF No. 147, p. 9). Further, they contend that Plaintiffs' causes of action do not arise out of any contacts Generic Defendants had with Missouri. (Id.).

Missouri's long-arm statute authorizes jurisdiction over any person or firm as to any cause of action arising from, among other things, that person or firm's "transaction of any business within this state" or "making of any contract within this state." Mo.Rev.Stat. §506.500.1(1),(2). The Missouri Supreme Court has held that the legislature intended the long-arm statute "to provide for jurisdiction, within the specific categories enumerated in the statutes, to the full extent permitted by the due process clause of the Fourteenth Amendment." State ex rel. Metal Serv. Ctr. of Georgia, Inc. v. Gaertner, 677 S.W.2d 325, 327 (Mo. 1984); see also Johnson v. Arden, 614 F.3d 785, 794 (8th Cir. 2010)("Missouri's long-arm statute, Mo.Rev.Stat. § 506.500, confers jurisdiction to the extent allowed by the Due Process Clause.").

In Aftanase v. Economy Baler Co., the Eighth Circuit set forth five factors courts must consider when determining whether there are sufficient minimum contacts to confer jurisdiction. 343 F.2d 187, 197 (8th Cir.1965); Johnson v. Arden, 614 F.3d 785, 794 (8th Cir. 2010). These factors include: (1) the nature and quality of the contacts with the forum state; (2) the quantity of

the contacts; (3) the relationship of the cause of action to the contacts; (4) the interest of Missouri in providing a forum for its residents; and (5) the convenience or inconvenience to the parties. Id. The first three factors are primary factors, and the remaining two factors are secondary factors. Id. The third factor distinguishes whether the jurisdiction is specific or general. Johnson, 614 F.3d at 794 (citing Digi–Tel Holdings, Inc. v. Proteq Telecomm., Ltd., 89 F.3d 519, 523 n. 4 (8th Cir.1996)). The Court "must look at all of the factors in the aggregate and examine the totality of the circumstances in making a personal-jurisdiction determination." Johnson, 614 F.3d at 794 (citing Northrup King Co. v. Compania Productora Semillas Algodoneras, S.A., 51 F.3d 1383, 1388 (8th Cir.1995)).

i. Specific Jurisdiction

"'Specific jurisdiction refers to jurisdiction over causes of action arising from or related to a defendant's actions within the forum state....'" Dairy Farmers of Am., Inc. v. Bassett & Walker Int'l, Inc., 702 F.3d 472, 475 (8th Cir. 2012)(quoting Miller v. Nippon Carbon Co., Ltd., 528 F.3d 1087, 1091 (8th Cir.2008)). "'Specific personal jurisdiction can be exercised by a federal court in a diversity suit only if authorized by the forum state's long-arm statute and permitted by the Due Process Clause of the Fourteenth Amendment.'" Dairy Farmers of Am., Inc., 702 F.3d at 475 (quoting Viasystems, Inc. v. EBM-Papst St. Georgen GmbH & Co., KG, 646 F.3d 589, 592 (8th Cir. 2011)).

"Specific jurisdiction over a defendant is exercised when a state asserts personal jurisdiction over a nonresident defendant that has purposefully directed [its] activities at [Missouri] residents in a suit that arises out of or relates to these activities." Johnson, 614 F.3d at 794 (citations and quotations omitted). Specific jurisdiction is proper "only if the injury giving rise to the lawsuit occurred within or had some connection to the forum state, meaning that the

defendant purposely directed its activities at the forum state and the claim arose out of or relates to those activities." Johnson, 614 F.3d at 795 (citing Steinbuch v. Cutler, 518 F.3d 580, 586 (8th Cir.2008)).

Generic Defendants contend that specific jurisdiction does not exist here because Generic Defendants committed no acts in Missouri allegedly giving rise to Plaintiffs' purported injuries. (ECF No. 147, p. 11). Absent any connection to the alleged injury within the State of Missouri, there can be no specific jurisdiction. (Id.). The Court agrees. Here, the cause of action alleged—that the Generic Defendants created and promoted a defective product that injured Kentucky plaintiffs—is entirely unrelated to their activities in Missouri. Rather, the cause of action "arises out of" and "relates to" activities in the State of Kentucky. As a result, Plaintiffs' argument for specific jurisdiction fails. Lakin, 348 F.3d at 707.

ii. General Jurisdiction

As discussed below, while the Generic Defendants' contacts with Missouri are unrelated to Plaintiffs' specific claims, the Court finds that their contacts with Missouri are sufficient to establish general jurisdiction. "To establish general jurisdiction over a foreign corporation, two elements must be satisfied: (a) service of process was obtained on the foreign corporation in the State of Missouri pursuant to section 506.150, RSMo 2000, and Rule 54.13(b)(3); and (b) the foreign corporation was doing substantial business in the State of Missouri." Wineteer v. Vietnam Helicopter Pilots Ass'n, 121 S.W.3d 277, 282 (Mo. Ct. App. 2003)(citing Collar v. Peninsular Gas Co., 295 S.W.2d 88, 90 (Mo.1956)). "The Missouri Supreme Court has held that general jurisdiction is properly asserted over an out-of-state corporation, under Missouri Law, when that corporation is 'present and conducting substantial business in Missouri.'" Viasystems, Inc., 646 F.3d at 595 (quoting State ex rel. K–Mart Corp. v. Holliger, 986 S.W.2d 165, 167 (Mo.

banc 1999)). "Because a corporation is a fictional entity, determining its "presence" can be conceptually difficult." Wineteer, 121 S.W.3d at 282 (citing K–Mart, 986 S.W.2d at 167). "The exercise of extraterritorial jurisdiction is permitted when a foreign corporation has certain 'minimum contacts' with the forum state. Wineteer, 121 S.W.3d at 282 (quoting Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945)).

"A court obtains general jurisdiction against a defendant who has continuous and systematic contacts with the forum state, even if the injuries at issue in the lawsuit did not arise out of the defendant's activities directed at the forum." Johnson, 614 F.3d at 794 (citations omitted); Goodyear Dunlop Tires Operations, S.A. v. Brown, 131 S. Ct. 2846, 2851 (2011)("A court may assert general jurisdiction over foreign (sister-state or foreign-country) corporations to hear any and all claims against them when their affiliations with the State are so 'continuous and systematic' as to render them essentially at home in the forum State."); Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 416 (1984)("continuous and systematic general business contacts required for general jurisdiction). "If a court has general jurisdiction over a defendant it can adjudicate any cause of action involving a particular defendant, regardless of where the cause of action arose." Viasystems, Inc. v. EBM-Papst St. Georgen GmbH & Co., KG, 646 F.3d 589, 595 (8th Cir. 2011)(citation omitted).

Generic defendants cite to two recent Supreme Court cases where the Court held there was not specific or general jurisdiction. Those cases, however, involved out-of-country corporate defendants who seemed to lack any connection to the forum state. For example, in Goodyear Dunlop Tires Operations, S.A. v. Brown, the Court held that "[b]ecause the episode-in-suit, the bus accident, occurred in France, and the tire alleged to have caused the accident was manufactured and sold abroad, North Carolina courts lacked specific jurisdiction to adjudicate

the controversy." 131 S. Ct. at 2851. The Supreme Court stated that "[a] connection so limited between the forum and the foreign corporation … is an inadequate basis for the exercise of general jurisdiction. Such a connection does not establish the 'continuous and systematic' affiliation necessary to empower [the State's] courts to entertain claims unrelated to the foreign corporation's contacts with the State." 131 S. Ct. at 2851. Thus, the Goodyear Court held that the foreign subsidiary did not have "continuous and systematic contacts" with the forum and, therefore, the Court lacked jurisdiction.

Likewise, in J. McIntyre Mach., Ltd. v. Nicastro, the Court framed the issue as "whether the New Jersey courts have jurisdiction over J. McIntyre, notwithstanding the fact that the company at no time either marketed goods in the State or shipped them there." 131 S. Ct. 2780, 2786 (2011). The injury occurred in New Jersey but the machine was manufactured by McIntyre in England. Id. Ultimately the Court held that "[a]t no time did petitioner engage in any activities in New Jersey that reveal an intent to invoke or benefit from the protection of its laws. New Jersey is without power to adjudge the rights and liabilities of J. McIntyre, and its exercise of jurisdiction would violate due process." 131 S. Ct. at 2791.

Based upon this precedent, Generic Defendants contend that this Court also lacks general jurisdiction over Plaintiffs' claims. They contend that "[g]eneral jurisdiction is proper only in a jurisdiction where the defendant is 'at home.'" (ECF No. 147, p. 11 (citing Goodyear, 131 S.Ct. at 2851)). Conversely, they note that "those who live or operate primarily outside a State have a due process right not to be subjected to judgment in its courts as a general matter." J. McIntyre Mach., Ltd., 131 S. Ct. at 2787. Because Missouri is not the Generic Defendants' "home," they assert that this Court does not have personal jurisdiction over Generic Defendants and this Court should dismiss this action as to them for lack of personal jurisdiction. (ECF No. 147, p. 11).

However, the Court does not regard a defendant's "home" as the only location where jurisdiction exists, as indicated by two decisions post-Goodyear and J. McIntyre. Although the Supreme Court has held that the defendant's home is the "paradigm forum" for the exercise of general jurisdiction for a corporation, the Court does not believe that this is the only location. In fact, the Eighth Circuit affirmed this position with its decision in Viasystems, where the Court analyzed the number of contacts that defendant had with Missouri, rather than summarily concluding that general jurisdiction did not exist because defendant was neither incorporated in Missouri or maintained a principal place of business in Missouri. Viasystems, 646 F.3d at 595-98. Ultimately, the Eighth Circuit held that where a foreign corporation "'pours its products into a regional distributor with the expectation that the distributor will penetrate a discrete, multi-State trade area,' … this connection alone is 'so limited' that it 'is an inadequate basis for the exercise of general jurisdiction.'" Id. at 597.

Plaintiffs outline various contacts with Missouri that they claim affords this Court with general jurisdiction. Plaintiffs state that, based upon the October 2008 label, Watson Pharma, Inc. distributed MCP that was manufactured by Barr Laboratories, Inc. (ECF No. 103, p. 14). Watson Pharma, Inc. is a foreign corporation, registered to do business in the state of Missouri. (Id.). Watson Pharma also has a designated personal agent for personal service of process within the state of Missouri. (Id.). Plaintiffs also note that Watson has twelve current or former employees who live and/or work in Missouri. (Id.).[3]

[3] Plaintiffs assert that, without the aid of discovery, Plaintiffs cannot resolve the relationship between Watson Pharma, Inc. and Watson Laboratories, Inc. Plaintiffs claim that "both entities appear to have distributed Reglan/MCP." (ECF No. 103, p. 14, n.5). Plaintiffs assert that "[o]nly discovery will reveal the volume of Watson Laboratories, Inc.'s prescription sales in Missouri and the relationship between the entities." (Id.).

Likewise, Plaintiffs contend that Teva (the owner of the Barr entities) is "the largest generic pharmaceutical company in the country" and that "[o]ne in six of the 2.6 billion generic prescriptions written in the United States is filled with a Teva product." (ECF No. 103, p. 15 (citing www.tevausa.com)). Plaintiffs contend that it "would strain common sense to believe that Teva does not conduct substantial business and derive significant revenue in Missouri." (ECF No. 103, p. 15). Plaintiffs also assert that Barr has employees who live and work in Missouri and that Barr participates in the MissouriRx program that provides prescription drugs to Missouri citizens. Based upon these contacts, Plaintiffs maintain that the Court should deny the motion to dismiss based upon lack of jurisdiction. (Id.).

At this stage of the litigation, the Court finds that Plaintiffs have demonstrated that Generic Defendants appear to have sufficient "continuous and systematic" contacts with the forum state for this Court to have general jurisdiction over their claims. The Court believes that, based upon these substantial contacts, it is reasonable to require Generic Defendants to defend this action in this Court. The Court denies Generic Defendants' Motion to Dismiss for Lack of Jurisdiction without prejudice.

b. Preemption of Claims against Generic Defendants

Generic Defendants contend that the United States Supreme Court's decision in Mensing requires dismissal of all of Plaintiffs' claims. (ECF No. 147, pp. 11-15). Generic Defendants rely heavily on the Sixth Circuit's determination in Smith v. Wyeth, Inc., 657 F.3d 420, 423 (6th Cir. 2011) that, under Mensing, federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims. (ECF No. 147, pp. 16-17).

Generic Defendants also contend that Plaintiffs' claims based upon their failure to update their labeling to include the 2004 FDA-mandated labeling revision to the branded Reglan are likewise preempted under Mensing. (ECF No. 147, pp. 18-19).[4] In addition, Generic Defendants claim that Plaintiffs' failure to update claims fail because they are premised solely on federal law and there is no state law duty for generic drug manufacturers to conform their labeling to that of the brand-name manufacturer. (ECF No. 147, p. 23).

Further, Generic Defendants maintain that Plaintiff's claims for negligence that purport to encompass more than just failure-to-warn claims are all barred because they are based upon federal statutes and regulations—not on state law. (ECF No. 147, pp. 27-28).[5] The Generic Defendants contend that but for the FDCA, no such requirements would exist. (Id.). However, they assert that Plaintiffs still have no cause of action for these non-failure-to-warn claims because federal law expressly states that there is no private right of enforcement under the FDCA. (Id.)(citing 21 U.S.C. §337(a)(proceedings for enforcement of FDCA "shall be by and in the name of the United States"); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001)). Likewise, Generic Defendants contend that, under Mensing, any attempts to enforce a purely federal duty under state law are prohibited. (ECF No. 147, p. 27). For example, any claimed duty that generic pharmaceutical companies should have asked the FDA to change the labeling for MCP was prohibited. (Id., pp. 27-28 (citing Mensing, 131 S.Ct. at 2578)).

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[4] In 2004, the FDA strengthened the Reglan label to warn: "**Therapy should not exceed 12 weeks in duration**."

[5] The Generic Defendants identify such claims as the following:

- Failing to reasonably design, manufacture, test, inspect, market, sell and/or distribute MCP so as to avoid the aforementioned risks to individuals.
- Failing to conduct adequate post-marketing surveillance to determine the safety of MCP.
- Failing to review and act upon all relevant scientific literature related to MCP.
- Failing to investigate the accuracy of their generic bioequivalent MCP products.
- Failing to reasonably and property conduct testing to determine the safety of MCP.

(ECF No. 147, p. 27 (citing Compl., ¶¶283, 285, 287(a), (d), and (h)).

Finally, Generic Defendants contend that Plaintiffs cannot maintain a design defect claim because they do not design the drugs and cannot change the design. (ECF No. 147, p. 34). In other words, Generic Defendants assert that a design defect claim is preempted because generic manufacturers cannot deviate from the approved design for the drug product.

In response, Plaintiffs state that their state law claims are not preempted under Mensing. (ECF No. 161, pp. 4-6; ECF No. 102). In particular, Plaintiffs assert that Mensing was purely a labeling case and their failure to warn claims are not preempted.

The Supremacy Clause of the United States Constitutional establishes federal law as "the supreme Law of the Land." U.S. Const., art VI, cl. 2. On June 23, 2011, the Supreme Court issued its decision in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011), holding that federal law pre-empted state laws imposing the duty on generic drug manufacturers to change a drug's label. Id., 131 S. Ct. at 2581. "Where state and federal law 'directly conflict,' state law must give way." Mensing, 131 S. Ct. at 2577(citing Wyeth v. Levine, 555 U.S. 555, 583(2009)). "[S]tate and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements.'" Mensing, 131 S. Ct. at 2577 (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287, 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995). The Supreme Court held that it was impossible for PLIVA and other generic manufacturers of MCP "to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Mensing, 131 S. Ct. at 2578.

Here, Plaintiffs attempt to distinguish Mensing by suggesting that their claims against Generic Defendants involve Generic Defendants' failure to include the updated 2004 warning in violation of their federal duty of sameness. In support of this position, Plaintiffs refer this Court to the Sixth Circuit's reasoning in Fulgenzi v. PLIVA, Inc. (ECF No. 198).

On March 13, 2013, the Sixth Circuit issued Fulgenzi v. PLIVA, Inc., 711 F.3d 578 (6th Cir. 2013). In that case, the plaintiff was prescribed the generic drug MCP for three months, starting in September 2004, and for over a year from 2006 to 2007. Id., 711 F.3d at 580. Initially, the only disclaimer on the label of Reglan was "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." Id. In July 2004, the FDA approved a labeling change proposed by Schwarz Pharma, the manufacturer of Reglan, which stated in bold-face type: "Therapy should not exceed 12 weeks in duration." The new warning appeared twice, as the first line in both the "Indications and Usage" and "Dosage and Administration" sections of the label. Id. "Apparently, PLIVA never updated its metoclopramide labeling to include the new warning, nor communicated the change to any physicians." Id. "In February 2009, the FDA went further and ordered a 'black-box warning'—the strongest form of warning the FDA requires—indicating the serious risk of developing tardive dyskinesia." Id. "The warning urged avoiding treatment longer than 12 weeks 'in all but rare cases where therapeutic benefit is thought to outweigh the risk of tardive dyskinesia.'" Id.

The Fulgenzi plaintiff alleged that PLIVA's failure to include the updated 2004 warning in its labeling was in violation of its federal duty of sameness, and that failure to update "'rendered its warnings inadequate under Ohio law.'" Id., 711 F.3d at 581. The Court held that Fulgenzi's claims survived only to the extent that PLIVA's actions were permitted by federal law. Id., 711 F.3d at 584. That is, the plaintiff could not claim that PLIVA should have included an aggressive black-box warnings as "any such allegations are preempted under Mensing." Id. Instead, the plaintiff was left to argue "only that PLIVA's warning was inadequate to the extent that it did not include the language contained in the updated Reglan label from 2004." Id.

The Sixth Circuit held that "it is uncontested that PLIVA's failure to update was in violation of its federal duty of sameness, and thus federal safety and effectiveness policies." Id., 711 F.3d at 586. Thus, the Sixth Circuit decided that "state laws that provide damages for inadequate warnings in violation of the federal duty of sameness do not conflict with federal drug policy, with respect to purposes-and-objectives preemption." Id.

The Sixth Circuit further held that the plaintiff's claim was not premised on violation of federal law, but rather on an independent state duty. Fulgenzi, 771 F.3d at 586-87. It determined that the plaintiff's case was based upon an inadequate warning and "would work equally well against a branded-drug manufacturer, or a generic-drug manufacturer whose branded counterpart had not updated its warning (of course, under Mensing the second case would be preempted under an impossibility theory)." Id., 771 F.3d at 587. Ultimately, the Sixth Circuit stated that Fulgenzi's claims were "viable only to the extent PLIVA should have included the language contained in the updated Reglan label by soon after July 2004, and that the failure to include that language proximately caused her injury." Id., 771 F.3d at 588).[6]

[6] The Court notes that two recent Eighth Circuit cases dismissed the plaintiffs' failure to update claims based upon the learned intermediary doctrine. See Fullington v. Pfizer, No. 12-2945, *11-12 (8th Cir. Jul. 15, 2013)(Eighth Circuit held that the learned intermediary doctrine barred Fullington's failure to update claim because she admitted that "her prescribing doctor relied upon information published in the package inserts and/or the Physicians' Desk Reference … or otherwise disseminated by the Reference Listed Drug Company."); Bell v. Pfizer, Inc., 716 F.3d 1087, 1098 (8th Cir. 2013)("Because Bell's physician prescribed Reglan and relied on its labeling, there is nothing to indicate Pliva's failure to update its warning affected Bell's physician's prescribing decision or Bell's injury in any way. Because there is no causal link between Pliva's failure to incorporate the 2004 labeling change and Bell's injury, the district court's dismissal of that claim was not error, regardless of whether Mensing preempted that claim."); see also Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (Ky. 2004)(detailing the rationale behind the learned intermediary doctrine and adopting it in prescription drug cases). While Generic Defendants seem to allude to the learned intermediary defense (ECF No. 147, pp. 21-22), the applicability of this argument to the instant case has not properly been developed. Moreover, the Court notes that the Generic Defendants filed a motion to dismiss, not a motion for summary judgment. The Court believes that the nature of the learned intermediary doctrine

As in Fulgenzi, Ms. Neeley's claims are both factually and legally distinguishable from Mensing. The Generic Defendants failed to include the following language: "Therapy should not exceed 12 weeks in duration" from the updated 2004 Reglan label. Thus, the Generic Defendants failed to conform their own labels to the 2004 FDA-mandated label change. As Ms. Neeley consumed MCP for longer than 12 weeks, this omission presents the gravamen of her cause of action against the Generic Defendants. Adopting the Sixth Circuit's reasoning in Fulgenzi, the Court finds that Plaintiffs' claims based upon violation of state duty for failure to update the MCP warning are not preempted by Mensing. Likewise, based upon Fulgenzi, the Court does not believe that Plaintiffs' "parallel claims" are veiled attempts to enforce violations of the FDCA and are not preempted by Buckman.[7]

In addition, at this stage of the litigation, the Court holds that the remaining claims for defective design are likewise not barred. Based upon the current law, the Court does not believe that these claims are preempted. See Mut. Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466

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focuses on Plaintiff's physician's knowledge at the time of prescribing. While the Court believes that Plaintiffs' allegations are sufficient to put the Generic Defendants on notice of the claims against them to satisfy Rule 8(a), the Court believes that the factual record must be more fully developed to determine whether the learned intermediary doctrine applies. See Compl., ¶88 ("Upon information and belief, in prescribing Reglan/MCP to the Plaintiff long-term and/or at high doses, Plaintiff's prescribing doctor relied upon information published in the package inserts and/or the Physicians' Desk Reference (hereinafter referred to as 'PDR') or otherwise disseminated by the Reference Listed Drug Company (hereinafter referred to as 'RLD') and/or the New Drug Application Holder (hereinafter referred to as 'NDA Holder')."). The Court believes that whether the learned intermediary doctrine applies here would be more properly addressed in a motion for summary judgment, as in Fullington v. Pfizer. Cf., Hyman & Armstrong, P.S.C. v. Gunderson, 279 S.W.3d 93, 110 (Ky. 2008)("it was error for the trial court to not submit a learned intermediary instruction because the instructions, as given, did not give the jury an opportunity to find whether Sandoz provided an adequate warning to Dr. Armstrong of the risks associated with Parlodel, which would have precluded a judgment against Sandoz under the law").

[7] See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 (2001)(fraud-on-the-agency claims are pre-empted).

(2013)("We do not address state design-defect claims that parallel the federal misbranding statute. The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is 'dangerous to health' even if 'used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.' 21 U.S.C. § 352(j)")(citing Bates v. Dow Agrosciences LLC, 544 U.S. 431, 447, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005) (state-law pesticide labeling requirement not pre-empted under express pre-emption provision, provided it was "equivalent to, and fully consistent with, [federal] misbranding provisions")). In Fullington v. Pfizer, No. 12-2945 (8th Cir. Jul. 15, 2013), the Eighth Circuit reversed the dismissal of the plaintiff's design defect claim and remanded the claim for further consideration based upon Arkansas law. No. 12-2945, p. 11. The Eighth Circuit noted that, under Arkansas law, courts focus on consumer expectations in determining whether a product is unreasonably dangerous, which was not addressed by the district court. Id. (citing Ark. Code Ann. §16-116-102(7)(A); Purina Mills, Inc. v. Askins, 875 S.W. 843, 847 (Ark. 1994); Berkeley Pump Co. v. Reed-Joseph Land Co., 653 S.W.2d 128, 133 (Ark. 1983)). Likewise, the Kentucky Supreme Court's analysis of defective design cases focuses on consumer expectations. McCarthy v. RiteScreen Co., Inc., 2011-CA-000888-MR, 2013 WL 2660783, at *7 (Ky. Ct. App. June 14, 2013) (citing Ulrich v. Kasco Abrasives Co., 532 S.W.2d 197, 200 (Ky.1976)). Accordingly, the Court denies the motion to dismiss regarding Plaintiffs' design defect allegations at this stage as "it is not immediately clear whether [Kentucky] … offers generic drug manufacturers an opportunity, consistent with federal obligations, to somehow alter an otherwise unreasonably dangerous drug." Fullington, No. 12-2945, p. 11.

Based upon the foregoing, the Court denies the Generic Defendants' Motion to Dismiss on Plaintiffs' claims for negligence, negligent misrepresentation and negligent supply of

information for the guidance of others (Count II), breach of warranty (Counts IV), misrepresentation and fraud (Count V), strict product liability (Count VIII), loss of consortium (Count XII), punitive damages (Count XIII), and Plaintiff's damages (Count XIV).[8]

**C. PEM Defendants**

Plaintiffs allege claims against Defendants Wolters Kluwer Health, Inc. ("WK Health") and Wolters Kluwer United States (WKUS") (collectively, "PEM Defendants") for negligence (Count VII), violation of the MMPA and/or KCPA (Count IX), joint and several liability, enterprise liability, market share liability, concert of action liability (Count X), breach of warranty (Count XI), loss of consortium (Count XII), punitive damages (Count XIII), and Plaintiff's damages (Count XIV). Plaintiffs assert that the PEM Defendants failed to warn of Regan/MCP's dangers when they published monograph information regarding the potential increased risk. (Compl., ¶¶116-18).

The PEM Defendants assert that they are entitled to dismissal of the claims against them for several reasons. First, they contend that Plaintiffs' only allegations against them stem from constitutionally protected speech. They assert that the First Amendment precludes tort liability against the publishers for nondefamatory and noncommercial speech. (ECF No. 145, p. 2). Second, they claim that, under Kentucky law, publishers of general information do not owe the reader or recipient of information any duty as a matter of law. (ECF No. 145, pp. 2-3). Third, they contend that the monograph on which Plaintiffs rely cannot establish liability. (ECF No. 145, p. 3). Fourth, Plaintiffs have not alleged facts sufficient to show they had a relationship with WK Health sufficient to support negligence or breach of warranty claim. (ECF No. 145, pp.

[8] The Court addresses Plaintiffs' MMPA and KCPA claims (Count IX) and claim for joint and several liability, enterprise liability, market share liability, concert of action liability (Count X) in a later section.

3-4). Fifth, Plaintiffs' claims are barred by the one year statute of limitations. (ECF No. 145, p. 4).

**1. Choice of Law**

This action is before the Court under diversity jurisdiction, 28 U.S.C. §1332. "'In a diversity action, a district court sitting in Missouri follows Missouri's choice-of-law rules to determine applicable state law.'" Wolfley v. Solectron USA, Inc., 541 F.3d 819, 823 (8th Cir. 2008)(quoting Stricker v. Union Planters Bank, 436 F.3d 875, 877 (8th Cir.2006)). "For tort claims, Missouri courts apply the 'most significant relationship' test." Wolfley v. Solectron USA, Inc., 541 F.3d 819, 823 (8th Cir. 2008)(citing Stricker v. Union Planters Bank, 436 F.3d at 878). "'Under this test, the identity of the state having the most significant relationship will depend upon the nature of the cause of action and upon the particular legal issue in dispute.'" Wolfley, 541 F.3d at 823 (quoting Dorman v. Emerson Elec. Co., 23 F.3d 1354, 1358 (8th Cir.1994)). "This formulation essentially establishes a presumption that the state with the most significant relationship is the state where the injury occurred, absent an overriding interest of another state based on the factors articulated in section 6." Dorman, 23 F.3d at 1358. In ascertaining whether such an overriding interest exists, the section 6 factors must be evaluated taking into account the contacts listed in section 145 according to their relative importance to the particular issue:

(a) the place where the injury occurred,
(b) the place where the conduct causing the injury occurred,
(c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and
(d) the place where the relationship, if any, between the parties is centered.

Dorman, 23 F.3d at 1358 (citing Kennedy v. Dixon, 439 S.W. 2d 173, 181 (Mo. 1969)(en banc); Restatement §145(2).

Under this test, the PEM Defendants contend that Kentucky has the most significant relationship to the dispute. Plaintiffs allege that they are residents of the State of Kentucky. (Compl., ¶2). Plaintiff was prescribed MCP in Kentucky, filled her prescriptions in Kentucky, ingested MCP in Kentucky, and suffered her injuries in Kentucky.

In response, Plaintiffs contend that Missouri law applies because there is no actual conflict between Kentucky and Missouri law. (ECF No. 160, p. 6). Where there is no conflict between the state's laws, then Missouri law should apply. Plaintiffs argue that Missouri law should apply because there is no conflict as both Missouri and Kentucky have adopted §324A of the Restatement (2d) of Torts. (ECF No. 160, p. 7).[9]

The Court finds no reason at this point to make a choice of law determination because it appears that the result would be the same for under either Missouri or Kentucky law. See ECF No. 171, p. 12 (noting that it may be "of no consequence" regarding whether Missouri or Kentucky law applies). The Court agrees that the parties have not identified a conflict between Missouri and Kentucky law. In particular, both Missouri and Kentucky have adopted the Restatement (Second) of Torts §324A.[10] Accordingly, the Court reviews Plaintiffs' claims against the PEM Defendants under both Missouri and Kentucky law.

**2. Discussion**

[9] However, in other pleadings related to other defendants, Plaintiffs admit that Kentucky law applies to this action. See, e.g., ECF No. 178, pp. 2-4.

[10] Restatement (Second) of Torts § 324A (1965) provides that:
One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if
(a) his failure to exercise reasonable care increases the risk of such harm, or
(b) he has undertaken to perform a duty owed by the other to the third person, or
(c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Most pharmacies provide written information (the Patient Education Monograph, or "PEM") to customers with each prescription dispensed. (Compl., ¶¶180, 336). Plaintiffs allege that the PEM Defendants contracted with Ms. Neeley's pharmacy to provide patient drug information in a written form available to customers at the time a prescription is picked up. (Compl., ¶181). The FDA does not regulate PEM authors. Rather, the PEM authors provided assurances in the early 1980s through the mid-1990s that they would "self-regulate" their conduct as to the form and substance of consumer medical information. (ECF No. 160, p. 3). As part of these assurances, a Steering Committee was created and developed a report titled Action Plan for the Provision of Useful Prescription Medicine Information (the "Keystone Guidelines."). (Compl., ¶185). Pursuant to these Guidelines, pharmacies and PEM authors are to provide PEMs that are (1) scientifically accurate, (2) unbiased in content and tone, (3) sufficiently specific and comprehensive, (4) presented in an understandable and legible format that is readily comprehensible to consumers, (5) timely and up-to-date, and (6) useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm. (ECF No. 160, p. 4; Compl., ¶187).

a. Legal Duty

The PEM Defendants claim that they owe no legal duty to Plaintiffs because Plaintiffs had no relationship with the PEM Defendants. (ECF No. 171, pp. 6-9). Likewise, the PEM Defendants assert that they have not assumed a legal duty to the readers of the PEM pamphlets. The PEM Defendants maintain that the Keystone Guidelines do not describe a clear set of rules for any particular warnings that should be included in a PEM. (ECF No. 171, p. 11).

In response, Plaintiffs contend that the PEM Defendants owed Ms. Neeley a duty as a matter of law. First, Plaintiffs state that the PEM Defendants are not merely "independent publishers".

(ECF No. 160, p. 13). Rather, Plaintiffs allege that the PEM Defendants "author[ed] consumer medication information specific to Reglan/MCP that [Ms. Neeley] and her healthcare providers relied upon." (Id.). Plaintiffs contend that the PEM Defendants "knew, or should have known, that those prescribing, dispensing and using Reglan/ MCP would rely upon its publications and databases." (Id.). Based upon this knowledge, Plaintiffs allege that, under a common law theory, the PEM Defendants, as PEM authors, assumed a duty to perform their contractual obligations in a manner as to avoid injury to third parties. (ECF No. 160, p. 14). Plaintiffs state that the PEM Defendants had a legal duty to Plaintiffs that "arises out of public policy factors, the clear foreseeability of the harm to the Plaintiff, and because [the PEM Defendants] voluntarily assumed a duty of care to the Plaintiff under the Restatement §324A, common law assumption of duty principles, the Keystone Guidelines, its purported expertise and advertising." (ECF No. 160, p. 19).

Upon motions to remand, several courts in this district have held that the collective plaintiffs' claims against the PEM Defendants and other PEM authors were "colorable," such that joinder of these defendants was not fraudulent. Lyons v. Wyeth, Inc., 4:11CV365 CDP, 2011 WL 2462071 (E.D. Mo. June 17, 2011); Nicely v. Wyeth, Inc., 4:11CV338 CDP, 2011 WL 2462060 (E.D. Mo. June 17, 2011); Farmer v. Wyeth, Inc., 411CV348CDP, 2011 WL 2462066 (E.D. Mo. June 17, 2011); Lawson v. Wyeth, Inc., 4:11CV364 RWS, 2011 WL 3608025 (E.D. Mo. Aug. 16, 2011); Newby v. Wyeth, Inc., 4:11CV00339 AGF, 2011 WL 5024572 (E.D. Mo. Oct. 21, 2011); Franzman v. Wyeth, Inc., 4:11-CV-362 CAS, 2011 WL 3847420 (E.D. Mo. Aug. 26, 2011). Those courts held that "colorable claims can be made against [the PEM defendant] under Missouri and Kentucky law arising from the materials it provided to accompany prescriptions of Reglan." Franzman, 2011 WL 3847420, at *2. While those cases were obviously before the

Court on a different standard of review than the present Fed.R.Civ.P. 12(b)(6) motion, the Court believes that these cases provide persuasive authority for finding a viable claim at this stage of the proceedings against the PEM Defendants. As in those cases, the PEM Defendants have not provided any Missouri or Kentucky authority declining to find a duty on behalf of the PEM defendants. Instead, the PEM Defendants rely on out of state cases decided on different grounds and/or different standards. See Rivera v. First DataBank, Inc., 187 Cal. App. 4th 709, 720 (2010)(in an anti-SLAPP lawsuit, the court held that plaintiffs "failed to substantiate their allegations that defendant owed them any duty vis-à-vis the monograph, which disposes of both causes of action"); Cheatham v. Teva Pharmaceuticals USA, 726 F. Supp. 2d 1021, 1024 (E.D. Ark. 2010)(granting defendant's summary judgment motion and holding that under Arkansas law "WKH's undertaking to provide patient drug education information to USA Drug Express did not create … a duty"); A.B. v. Ortho-McNeil-Janssen Pharmaceuticals, No. 649, 2013 Phila. Ct. Com. Pl. LEXIS 84 (Apr. 5, 2013)(granting the PEM publisher's motion for summary judgment after the close of discovery).[11]

The Court finds that, at this stage of the litigation, Plaintiffs have sufficiently stated a duty owed to Plaintiffs. Even though the PEM Defendants did not have a direct relationship with Plaintiffs, the Court finds that Plaintiffs were foreseeable recipients of information provided by the PEM Defendants. The Court holds that Plaintiffs adequately allege that they were foreseeable third-party beneficiaries based upon the "clear foreseeability of harm to Plaintiff" and because the PEM Defendants "voluntarily assumed a duty of care to Plaintiff under the Restatement §324 and common law assumption of duty principles." (ECF No. 160, p. 19);

[11] Notably, Wilkow v. Drug Fair, Inc., L-2137-98, 1999 WL 33645138 (N.J. Super. Ct. Law Div. Oct. 22, 1999) is a one-page order that provides no analysis regarding the court's grant of summary judgment.

Pierce v. Platte-Clay Elec. Co-op., Inc., 769 S.W.2d 769, 776 (Mo. 1989)("a duty exists when a general type of event or harm is foreseeable"); Grayson Fraternal Order of Eagles, Aerie No. 3738, Inc. v. Claywell, 736 S.W.2d 328, 332 (Ky. 1987)("every person owes a duty to every other person to exercise ordinary care in his activities to prevent foreseeable injury"). The PEM Defendants have cited to no relevant case law to find that they did not owe a duty to Plaintiffs under these circumstances. Accordingly, the Court finds that Plaintiffs' allegations against the PEM Defendants survive the motion to dismiss.

b. First Amendment

The PEM Defendants claim that the PEMs are entitled to First Amendment protection, that they are not "commercial speech" simply because WK Health licenses them for profit and, even if the PEMs were "commercial speech," they would be entitled to protection because Plaintiffs do not allege that they were false (as opposed to incomplete). (ECF No. 145, p. 9; ECF No. 171, pp. 11-12) The PEM Defendants further assert that the First Amendment protects publishers, not just the press, from similar claims. (ECF No. 171, p. 12). Finally, the PEM Defendants contend that WK Health merely publishes PEMs based on information published by a drug manufacturer and approved by the FDA.

In response, Plaintiffs argue that the First Amendment is not applicable because Plaintiffs do not seek an injunction, but merely tort liability. In addition, Plaintiffs contend that the PEM Defendants are authors, not merely publishers, and therefore they are not protected by the publisher liability cases cited by the PEM Defendants. (ECF No. 160, p. 32 (asserting that the PEM Defendants are responsible for the content of its PEMs and are not merely publishers of FDA drug information)).

The Court finds that a factual dispute precludes summary judgment in this case. It is unclear whether the PEM Defendants are publishers or authors. Plaintiffs allege that the PEMs were "created, authored, written, edited, provided and made available to those pharmacies by the PEM Defendants, pursuant to agreement, formal or informal, written or unwritten, between Plaintiffs' pharmacies and PEM Defendants, or otherwise, for purposes of providing same to Plaintiff's pharmacy's customers, including the Plaintiff." (Compl., ¶335). As Plaintiffs allege that the PEM Defendants were authors and not simply publishers, the Court finds that the First Amendment case law cited by Plaintiffs does not mandate dismissal of the claims against the PEM Defendants and the Court denies the motion to dismiss on this basis.

c. Adequacy of the Warnings

The PEM Defendants maintain that their warnings summarized the FDA warnings and, therefore, the warnings provided are not actionable. The Court finds that this defense presents an issue of fact that is not proper at the motion to dismiss stage. See Moore v. Ford Motor Co., 332 S.W.3d 749, 762 (Mo. 2011); Larkin v. Pfizer, Inc., 153 S.W.3d 758, 770 (Ky. 2004).

d. Kentucky Statute of Limitations

The PEM Defendants assert that Kentucky's one-year statute of limitations applies and bars Plaintiffs' claims. The PEM Defendants contend that Plaintiffs' claim against WK Health accrued when Plaintiffs "should have discovered that Ms. Neeley had involuntary movements that were for some reason insufficiently explained in WK Health's PEM." (ECF No. 171, pp. 13-14). Consequently, the PEM Defendants insist that Plaintiffs' causes of action should have been discovered before February 2009.

Plaintiffs state that the "discovery rule" precludes granting a motion to dismiss. "[U]nder the 'discovery rule,' a cause of action will not accrue until the plaintiff discovers (or in the exercise

of reasonable diligence should have discovered) not only that he has been injured, but also that this injury may have been caused by the defendant's conduct." Fluke Corp. v. LeMaster, 306 S.W.3d 55, 60 (Ky. 2010)(citation omitted). "Accrual of the cause of action is dependent upon the plaintiff's knowledge that not only has he suffered an injury but also who caused the injury." R.T. Vanderbilt Co., Inc. v. Franklin, 290 S.W.3d 654, 659 (Ky. Ct. App. 2009)(citing Wiseman v. Alliant Hosps., Inc., 37 S.W.3d 709, 712 (Ky.2000)).

Plaintiffs claim that their causes of action began to accrue no earlier than February 2009 when Ms. Neeley would have learned of the causal connection between the product and her tardive dyslexia. While the PEM Defendants claim that Plaintiffs' cause of action began to accrue when Ms. Neeley began experiencing involuntary movements, Plaintiffs contend that it began to accrue when the 2009 black box warning was added to the Reglan/MCP label. (ECF No. 160, pp. 9-10). Plaintiffs state that they could not have known that Ms. Neeley's injuries were the result of long-term use of Reglan/MCP until the FDA's black box warning in February 2009. (ECF No. 160, p. 10).

The Court finds that, at this stage of litigation, when Plaintiffs' causes of action began to accrue presents an issue of fact for the jury to decide. See Lipsteuer v. CSX Transp., Inc., 37 S.W.3d 732, 737 (Ky. 2000)(when the plaintiff was put on notice about the cause of his injury is "a question of fact and should therefore be answered by a jury")(citing Lynn Mining Co. v. Kelly, Ky., 394 S.W.2d 755, 759 (1965)). At a minimum, for purposes of a motion to dismiss, the Court cannot determine as a matter of law that Plaintiffs should have known that their causes of action had accrued prior to February 2009. Therefore, the Court denies the PEM Defendants' Motion to Dismiss on this basis.

e. Missouri and Kentucky Consumer Protection Act Claims

Finally, the PEM Defendants state that Plaintiffs' Missouri Merchandise Practices Act (MMPA) claims fail. First, the PEM Defendants note that none of the allegedly fraudulent activity took place in Missouri. Likewise, none of Plaintiffs' injuries arose in Missouri. PEM Defendants assert that without such allegations, a MMPA claim fails as a matter of law. (ECF No. 171, p. 15).

In response, Plaintiffs contend that the MMPA is designed to protect Missouri citizens from economic activity that has a direct or indirect effect on them. (ECF No. 160, p. 38). Plaintiffs state that the MMPA's definition of "trade or commerce" in section 407.010(7) "simply makes clear the intent of the General Assembly that the terms should be understood to include, but not necessarily be limited to, economic activity which has a direct or indirect effect on the people of this state." State ex rel. Nixon v. Estes, 108 S.W.3d 795, 800 (Mo. Ct. App. 2003). Thus, Plaintiffs contend that MMPA claims are not limited to intrastate activities or intrastate effects and that the PEM Defendants "engaged in the same unfair conduct when selling and providing Reglan/MCP PEMs in Missouri to thousands of Missouri residents." (ECF No. 160, p. 39). In addition, Plaintiffs aver that they sufficiently allege that the PEM Defendants were involved in the marketing, promoting and selling of Reglan/MCP. (ECF No. 160, p. 39 (citing Compl., ¶¶181, 336, 366). Plaintiffs state that the PEMs were used to perform pharmacy counseling and education and, therefore, were "inextricably linked to the 'marketing, promoting or selling' of Reglan/MCP." (ECF No. 160, p. 39). Thus, at this stage of the litigation, Plaintiffs contend that they have alleged sufficient facts to support a MMPA claim against the PEM Defendants.

In addition, the PEM Defendants state that Plaintiffs' KCPA claim fails. The PEM Defendants note that the KCPA prohibits "unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." Ky.Rev.Stat. §367.170. "Trade" and "commerce" are

defined as "advertising, offering for sale, or distribution" of services or property or other thing of value. Ky.Rev.Stat. §367.110(2). The PEM Defendants argue that there is no allegation that WK Health advertised, sold, or distributed Reglan or any other product to Plaintiffs. (ECF No. 171, p. 15). Similarly, the PEM Defendants instruct that the KCPA only provides a private cause of action against a seller of merchandise. (Id.)(citing Skilcraft Sheetmetal, Inc. v. Kentucky Mach., Inc., 836 S.W.2d 907, 909 (Ky. Ct. App. 1992)). As they were not the immediate sellers of Reglan or other products, the PEM Defendants argue that Plaintiffs' KCPA claims fail as a matter of law.

Conversely, Plaintiffs contend that there is no "immediate purchaser" requirement to assert a violation under the KCPA. (ECF No. 160, p. 39). Rather, Plaintiffs maintain that the privity requirement can be disregarded where the plaintiffs are individuals who are treated like consumers and fall into the class of individuals which the KCPA is intended to protect. (ECF No. 160, p. 40 (citing Stafford v. Cross Country Bank, 262 F. Supp. 2d 776, 793 (W.D. Ky. 2003)("the Kentucky legislature created a statute which has the broadest application in order to give Kentucky consumers the broadest possible protection for allegedly illegal acts")). Plaintiffs state that they have alleged that the PEM Defendants' conduct was for the intended benefit of the pharmacy's patients. Therefore, Plaintiffs maintain that privity is present because they are the intended third party beneficiary of any contract between the PEM Defendants and Ms. Neeley's pharmacy for the distribution of PEMs. (ECF No. 160, p. 40). Plaintiffs state that this argument equally applies to Plaintiffs' breach of warranty claim as well as Plaintiffs' "derivative claims, including the punitive damages claim." (Id.).

First, the Court finds that Plaintiffs fail to state a claim under the MMPA against the PEM Defendants. Although the scope of the MMPA is broad, it is not without limits. The MMPA

states that "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose, as defined in section 407.453, in or from the state of Missouri, is declared to be an unlawful practice." Mo.Rev.Stat. 407.020.1. Here, the alleged activity and fraud had absolutely no connection "in or from the state of Missouri." See State ex rel. Nixon v. Estes, 108 S.W.3d at 800 ("it is not so much the definition of 'trade or commerce' which ultimately establishes the reach of section 407.020.1 as it is its requirement that the trade or commerce originate or occur 'in or from the state of Missouri'"). Plaintiffs' argument that similar acts were performed in the state of Missouri is without merit as such claims are not before this Court. Accordingly, the Court dismisses the MMPA claim against the PEM Defendants.

Conversely, the Court finds that Plaintiffs state a KCPA claim against the PEM Defendants. Ky.Rev.Stat. §367.170 proclaims, "Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." Under the KCPA,

> Any person who purchases or leases goods or services primarily for personal, family, or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful by KRS 367.170, may bring an action ... to recover actual damages. The court may, in its discretion, award actual damages and may provide such equitable relief as it deems necessary or proper.

Ky.Rev.Stat. § 367.220(1). The KCPA "is remedial legislation enacted to give consumers broad protection from illegal acts." Skilcraft Sheetmetal, Inc. v. Kentucky Mach., Inc., 836 S.W.2d 907, 909 (Ky. Ct. App. 1992)(citing Stevens v. Motorists Mut. Ins. Co., Ky., 759 S.W.2d 819, 821 (Ky. 1988)). "[B]y its very terms, the KCPA requires only that the plaintiff prove that he or

she suffered an 'ascertainable loss' that was the 'result' of the allegedly deceitful practice of the defendant." Corder v. Ford Motor Co., 869 F. Supp. 2d 835, 838 (W.D. Ky. 2012).

The Court determines that Plaintiffs sufficiently allege a deceptive practice under the KCPA. The Court finds that the PEM Defendants' alleged actions fall within the scope of activities to be protected against by the KCPA and Plaintiffs, as intended beneficiaries, are within the protected class of persons to be protected by the act. Plaintiffs have alleged that the PEM Defendants provided false or misleading PEMs and that Plaintiffs were injured as a result thereof. See, e.g., Compl., ¶¶180-211, 363-67. The Court also finds that privity exists between the PEM Defendants and Plaintiffs because Plaintiffs were intended third party beneficiaries. See Louisville Gas & Elec. Co. v. Cont'l Field Sys., Inc., 420 F. Supp. 2d 764, 770 (W.D. Ky. 2005)("An actual and direct promise for the benefit of a third party will be sufficient to create privity between the promisor and the third party beneficiary."). Accordingly, the Court denies the PEM Defendants' motion to dismiss with respect to the KCPA.

f. WKUS

The PEM Defendants note that WKUS is a corporate entity separate and distinct from WK Health. (ECF No. 145, p. 1, n.1). The PEM Defendants note that "[o]ther than Plaintiffs' conclusory allegation that WKUS 'individually or through WK [Health], was engaged in the regular business of providing patient drug information,' the Second Amended Complaint alleges no facts showing what WKUS was in fact involved in any of the events described therein." (Id. (citing Compl., ¶11)). The PEM Defendants assert that "WK Health is the only … company involved in published patient education information or any other drug information" and, therefore, "Plaintiffs' improper group pleading and insufficient investigation are insufficient to require WKUS to continue to participate in this action. (Id.).

In response, Plaintiffs contend that they have adequately alleged WKUS and WU Health are both "PEM authors in the business of creating, publishing and authoring Reglan/MCP drug information." (ECF No. 160, p. 1, n.1). Plaintiffs maintain that they alleged that WKUS provides and disseminates Reglan/MCP information. (Id.). Consequently, Plaintiffs assert that dismissal of WKUS is premature until Plaintiffs have an opportunity to conduct discovery. (Id.).

The Court agrees that dismissal of WKUS would be premature at this juncture. As this case is before the Court on a motion to dismiss, the Court must assume Plaintiffs' allegations against WKUS are true and finds that Plaintiffs' allegations are sufficient to state a claim against WKUS.

In conclusion, the Court denies the PEM Defendants' Motion to Dismiss for negligence (Count VII), violation of the KCPA (Count IX), breach of warranty (Count XI), loss of consortium (Count XII), punitive damages (Count XIII), and Plaintiff's damages (Count XIV). The Court grants the PEM Defendants' Motion to Dismiss with respect to Plaintiffs' MMPA claim in Count IX. [12]

D. **Motion to Dismiss Based Upon Insufficient Allegations**[13]

**1. Claims Based "Upon Information and Belief"**

Defendants claim that Plaintiffs have not alleged facts to satisfy the pleading requirements under Fed.R.Civ.P. 8(a)(2). (ECF No. 149, p. 3). Rather, Defendants criticize Plaintiffs for alleging that "upon information and belief," Ms. Neeley ingested MCP

[12] The Court addresses Plaintiffs' claim for joint and several liability, enterprise liability, market share liability, concert of action liability (Count X) in a later section.

[13] Barr Laboratories, Inc. Barr Pharmaceuticals, LLC, Watson Laboratories, Inc., Wolters Kluwer Health, Inc, and Wolters Kluwer United States, Inc. originally filed this Motion to Dismiss Based Upon Insufficient Allegations. (ECF No. 148). Thereafter, Watson Pharma, Inc. joined in the Motion to Dismiss. (ECF No. 167). The Court refers to the defendants filing the Motion to Dismiss Based Upon Insufficient Allegations generally as "Defendants".

manufactured by Barr Laboratories, Barr Pharmaceuticals, and Watson Laboratories, that "upon information and belief" she ingested MCP for longer than 12 weeks, and that "upon information and belief" WK Health and/or WKUS authored the PEMs used by her pharmacy. (ECF No. 149, p. 4)(citing Compl., ¶¶73, 75, 76, 77). Defendants criticize Ms. Neeley for not identifying the product she ingested, the duration of her use of the product, the pharmacies she used, what PEMs she read, or any injuries resulting from her tardive dyskinesia. (ECF No. 149, pp. 4-6).

The Court finds that Plaintiffs' factual allegations are sufficient to satisfy the Fed.R.Civ.P. 8(a)(2) standard. Only 24 out of the 346 paragraphs are based "upon information and belief." (ECF No. 158, p. 6). Plaintiffs have clarified that Ms. Neeley only ingested the generic MCP. And, Plaintiffs have provided numerous pharmacy records that outline Ms. Neeley's use of MCP. Based upon the foregoing, the Court believes that Plaintiffs have provided facts sufficient to state causes of action against Defendants and provide fair notice to Defendants of the claims against them.

**2. Consumer Protection Statutes**

Defendants next claim that Plaintiffs' consumer production act claims under the MMPA and the KCPA (Count IX) fail because they do not comply with Fed.R.Civ.P. 8 or Rule 9(b)'s heightened pleading standards for fraud and misrepresentation claims. (ECF No. 149, p. 7). Defendants contend that Plaintiffs allege mere legal conclusions and do not connect any violations to their injuries. (Id.). Finally, Defendants state that Plaintiffs' claim for violation of the MMPA is not valid because Plaintiffs allege no connection to a sale or advertisement of merchandise within in the state of Missouri. (ECF No. 149, p. 8).

The Court finds that Plaintiffs sufficiently allege their KCPA claims against the Defendants. Plaintiffs allege that the Defendants' Reglan/MCP drug information was false and

misleading and caused her to ingest MCP for longer than 12 weeks, which ultimately caused her to develop tardive dyskinesia. (ECF No. 158, pp. 15-17). The Court finds Plaintiffs' Complaint alleges this fraud and/or misrepresentation with sufficient particularity. (Compl., ¶¶162, 207-08, 211-16, 314-22, 314-22, 335-48). The Court, however, agrees that Plaintiffs fail to allege a valid MMPA claim. As previously discussed, Plaintiffs' purported MMPA claim lacks any connection to any commerce in Missouri. Plaintiffs do not reside in Missouri and never ingested Reglan/MCP in Missouri. As Plaintiffs' claims have no connection to Missouri, the Court dismisses their MMPA claims against all Defendants. See State ex rel. Nixon v. Estes, 108 S.W.3d at 800.

**3. Market Share Liability/Enterprise Liability and Concert of Action Liability Claims**

Defendants contend that Plaintiffs' claim in Count X for "Joint and Several Liability, Enterprise Liability, Market Share Liability, Concert of Action Liability" is invalid. (ECF No. 149, p. 8). Defendants state that Kentucky has rejected any industry-wide theory of liability. (ECF No. 149, pp. 8-9)(citing Farmer v. City of Newport, 748 S.W.2d 162, 165 (Ky. Ct. App. 1988); Zafft v. Eli Lilly Co., 676 S.W.2d 241 (Mo. 1984)). Defendants also assert that Plaintiffs have not alleged any agreement between manufacturers, which is required under a "concert of action" tort. (ECF No. 149, p. 9 (citing Farmer, 748 S.W.2d at 164).

In response, Plaintiffs assert that Kentucky law does not apply to Plaintiffs' claims. In addition, Plaintiffs maintain that Farmer v. City of Newport does not preclude enterprise liability under all circumstances—just "in this case." 748 S.W.2d at 165. Finally, Plaintiffs contend that to state a "concert of action" claim Plaintiffs must simply show "joint activity" between Defendants, which can include an "agreement existed between the manufacturers." Farmer v., 748 S.W.2d at 164; Zafft, 676 S.W.2d at 245. Plaintiffs assert that they have shown this by

alleging that Defendants "jointly conspired in designing and manufacturing the drug and concealing its dangerous side effects in a manner that injured the Plaintiff." (ECF No. 158 (citing Compl., ¶¶125, 211-24, 368-71)).

Based upon Plaintiffs' response, it seems to the Court that Plaintiffs are only trying to proceed under a "concert of action" theory.[14] Defendants claim that Plaintiffs' general allegations that Plaintiffs jointly conspired and concealed the dangerous side effects of MCP is insufficient. (ECF No. 169, p. 10). In fact, Plaintiffs allege simply that "[b]y virtue of their individual and collective acts and omissions, Defendants are liable to Plaintiff under the theory of Enterprise and/or Market Share liability… [and] are liable for acting in concert with one another in a way that resulted in Plaintiff's harm" (Compl., ¶¶370-71). The Court finds that these allegations, as presently set forth, are insufficient to state a cause of action under a concert of action theory because Plaintiffs do not allege that an agreement existed between the manufacturers. Farmer, 748 S.W.2d at 164.[15] The Court, therefore, dismisses Count X as to all defendants, without prejudice.

## II. Motion for Summary Judgment

### A. Standard of Review

The Court may grant a motion for summary judgment if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Citrate, 477 U.S. 317, 322 (1986); Torgerson v. City of Rochester, 643 F.3d 1031, 1042 (8th Cir. 2011). The substantive law

[14] The Court also notes that Farmer and Zafft reject a cause of action under the theory of enterprise liability.

[15] This Court has determined that Kentucky law applies to the claims against the Generic Defendants and the Brand Defendants.

determines which facts are critical and which are irrelevant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Only disputes over facts that might affect the outcome will properly preclude summary judgment. Id. Summary judgment is not proper if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Id.

A moving party always bears the burden of informing the Court of the basis of its motion. Celotex Corp., 477 U.S. at 323. Once the moving party discharges this burden, the nonmoving party must set forth specific facts demonstrating that there is a dispute as to a genuine issue of material fact, not the "mere existence of some alleged factual dispute." Fed. R. Civ. P. 56(e); Anderson, 477 U.S. at 248. The nonmoving party may not rest upon mere allegations or denials of his pleading. Anderson, 477 U.S. at 258.

In passing on a motion for summary judgment, the Court must view the facts in the light most favorable to the nonmoving party, and all justifiable inferences are to be drawn in his favor. Celotex Corp., 477 U.S. at 331. The Court's function is not to weigh the evidence but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. "'Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.'" Torgerson, 643 F.3d at 1042 (quoting Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000)).

**B. Choice of Law**

The parties do not seem to dispute that Kentucky law applies to Plaintiffs' claims against the Brand Defendants. (ECF No. 176, p. 18; ECF No. 178, p. 2). Accordingly, the Court applies Kentucky law.

**C. Discussion**

Plaintiffs bring claims against the Brand Defendants for negligence, negligent misrepresentation and negligent supply of information for the guidance of others (Count I), breach of warranty (Count III), misrepresentation and fraud (Count VI), strict product liability (Count VIII), violation of the MMPA and/or KCPA (Count IX), joint and several liability, enterprise liability, market share liability, concert of action liability (Count X), and loss of consortium (Count XII), punitive damages (Count XIII), and Plaintiff's damages (Count XIV). It is undisputed that Ms. Neeley never took the brand name Reglan product. (ECF No. 164). Nevertheless, Plaintiffs assert that the Brand Defendants should be liable because they developed allegedly misleading warnings for Reglan, and ultimately MCP (often referred to as "innovator liability" or, as Plaintiffs refer to it "Drug Designer Liability"). (ECF No. 178, p. 10).

Plaintiffs contend that Brand Defendants are liable to them on several theories, which are not grounded in strict products liability: 1) negligence, 2) negligent misrepresentation, and 3) negligent supply of information. (ECF No. 178, p 14). Plaintiffs contend that traditional product liability law should not be used to immunize the Brand Defendants. (ECF No. 178, p. 10). Rather, Plaintiffs claim that their action is based upon the Brand Defendants' conduct and that common law negligence elements (duty, breach, causation and damages) should apply. Plaintiffs contend that relevant and applicable Kentucky and Sixth Circuit law does not preclude liability against the Brand Defendants. Specifically, Plaintiffs assert that products liability law should not apply to their negligence actions against the Brand Defendants because their claims relate to the Brand Defendants' conduct, not their product (which Ms. Neeley obviously did not ingest). (ECF No. 178, pp. 24-36; see, e.g., ECF No. 178, p. 29 ("To hamstring the Plaintiff by pigeon-holding the claim as one grounded in products ability simply because a product was the physical cause of the injury, ignores that Plaintiff's ordinary negligence, misrepresentation and fraud

claims are based upon the Brand Defendants' conduct that is separate and distinct from the manufacture, sale or distribution of the product that injured Plaintiff—but still remains a cause of Plaintiff's injury.").

First, Plaintiffs assert the Brand Defendants owed a duty to them even though the Brand Defendants had no direct relationship with Plaintiffs, *i.e.*, even though Ms. Neeley never ingested the Brand Defendants' product, Reglan. Plaintiffs assert that the "existence of a duty under Kentucky law is more properly based on *public policy factors* and *the foreseeability of the harm* to the plaintiff. (ECF No. 178, p. 17 (emphasis in original)). Plaintiffs contend that a duty exists in this case because it was foreseeable to the Brand Defendants that misrepresentations regarding Reglan could result in personal injury to users of Reglan's generic equivalents. Likewise, Plaintiffs assert that protecting consumers from dangerous products is the public policy of Kentucky. Plaintiffs assert that "allowing both the Brand and the Generic Defendants to escape liability defies common sense and the realities of the drug industry." (ECF No. 178, p. 23).

Second, Plaintiffs contend that the Brand Defendants breached their duty. Plaintiffs assert that "[d]espite being aware of the dangers, Brand Defendants represented that Reglan/MCP was safe to treat gastritis/gastroesophageal reflux knowing that the contrary was true." (ECF No. 178, p. 13).

The Court, however, finds that Kentucky law mandates product identification for liability against the Brand Defendants. The Court discerns that Kentucky state courts would decline to find such liability where the plaintiff did not utilize the product. See Morgan v. Scott, 291 S.W.3d 622, 631 (Ky. 2009)("duty … is not without limits.… we remain committed to the longstanding tort principle that liability based upon negligence is premised upon the traditional prerequisites, such as proximate cause and foreseeability"). The Court finds that "to impose a

duty in the circumstances of this case would be to stretch the concept of foreseeability too far." Foster v. Am. Home Products Corp., 29 F.3d 165, 171 (4th Cir. 1994). Likewise, the Court does not believe that Plaintiff's "public policy" argument precludes entry of summary judgment. It is not for this Court to dictate public policy. See Karas v. Am. Family Ins. Co., Inc., 33 F.3d 995, 1000 (8th Cir. 1994)("our role is to interpret state law in diversity cases and not to fashion it").[16]

Although Plaintiffs would like to take the focus of this case away from the product at issue, the Court finds that under Kentucky's Product Liability Act ("PLA") there must be a product that caused Plaintiffs' injury, no matter how they label their causes of action. Under Kentucky's PLA, "a 'product liability action' shall include any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any product." Ky.Rev.Stat. §411.300(1). As the Kentucky Supreme Court has observed, "[t]he PLA applies to all damage claims arising from the use of products, regardless of the legal theory advanced." Monsanto Co. v. Reed, 950 S.W.2d 811, 814 (Ky. 1997).

Further, although Plaintiffs emphasize the non-binding nature of the decision in Smith v. Wyeth, the Court finds its reasoning to be sound and applicable in this instance. In Smith, the plaintiffs sued brand-name Reglan manufacturers on the theories of "fraud, fraudulent concealment, and negligent misrepresentation." Smith v. Wyeth, Inc., 657 F.3d 420, 422 (6th Cir. 2011). In Smith, the Sixth Circuit affirmed the district court's holding that "adopting [the

[16] Brand Defendants note that Plaintiffs alleged a strict liability claim against them. (ECF No. 183, p. 10, n.2). Although it is not mentioned by Plaintiffs in their briefing, the strict liability claim fails because Ms. Neeley did not use the brand-name products. See Holbrook v. Rose, 458 S.W.2d 155, 157 (Ky. 1970)("Proof of legal causation is required in cases involving liability for products including drugs").

name-brand defendants'] theory of liability would require the court to attribute any deficiency in a name-brand manufacturer's labeling and marketing of its products to products manufactured by its generic competitors. Such a theory, however, fails to satisfy the threshold requirement of a products-liability action—that the *defendant's* product have injured the plaintiff." Smith, 657 F.3d at 423. Further, the Sixth Circuit noted that "plaintiffs' argument—that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs—has been rejected by all but one of the courts that have considered it." Smith, 657 F.3d at 423-24. Siding with the majority of courts, the Sixth Circuit "reject[ed] the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company." Smith, 657 F.3d at 424. Likewise, the Sixth Circuit held that "the state courts of Kentucky would [not] adopt [the name-brand defendants'] vicarious-liability argument under the Kentucky Products Liability Act." Id.

This Court agrees with the Sixth Circuit that the "threshold requirement" that a product-liability plaintiff must prove that "the *defendant's* product caused the plaintiff's injury." Smith, 657 F.3d at 423 (emphasis in original). Courts applying Kentucky law have also required that the defendant's product have caused the injury. See Bryant v. Tri-Cnty. Elec. Membership Corp., 844 F. Supp. 347, 354 (W.D. Ky. 1994)(granting defendant Kuhlman's motion for summary judgment where plaintiffs "offer[ed] no evidence regarding the distinctive characteristics of the original transformers which would allow a reasonable jury to decide that they were made by Kuhlman rather than by any one of five other manufacturers"); Snawder v. Cohen, 749 F. Supp. 1473, 1479 (W.D. Ky. 1990)("In product liability suits brought in Kentucky, causation is an essential element of the plaintiff's case, regardless of the theory of

recovery propounded."); Albright v. Upjohn Co., 788 F.2d 1217, 1219 (6th Cir. 1986). Accordingly, the Court agrees with Smith that Plaintiffs cannot recover from the Brand Defendants because Ms. Neeley only ingested generic MCP made by other companies, not Reglan.[17]

The Eighth Circuit has also held likewise. In Bell v. Pfizer, Inc., 716 F.3d 1087 (8th Cir. 2013), the Court held that to prove her "product liability claims under Arkansas law, Bell must show that a product manufactured or distributed by the brand defendants caused her injuries." Id. at 1092. Like Kentucky, Arkansas law requires that to prove a product liability claim a plaintiff must show that a product manufactured or distributed by the brand defendants caused her injuries. Id. (citing Chavers v. Gen. Motors Corp., 349 Ark. 550, 79 S.W.3d 361, 369–70 (2002); Jackson v. Anchor Packing Co., 994 F.2d 1295, 1303 (8th Cir.1993)). Because Bell never used Reglan the brand defendants manufactured, the Eighth Circuit held that Bell could not hold them liable under Arkansas law. Bell, 716 F.3d at 1093.

The Eighth Circuit also held that the brand defendants were entitled to summary judgment on Bell's negligence claims because she failed to establish the brand defendants "owed her a duty of care necessary to trigger liability" under Arkansas law. Bell, 716 F.3d at 1093. Although a manufacturer may owe a duty to the ultimate user of its product, the Court held that "nothing in Arkansas law … supports extending such a duty of care to the customer of a competitor using a competing product." Id. (citing Mensing v. Wyeth, Inc., 588 F.3d 603, 613–14 & n. 9 (8th Cir. 2009)).

[17] This Court also recognizes Judge Murphy's concurrence in Fullington v. Pfizer, No. 12-2945, p. 12-14) (8th Cir. Jul. 15, 2013), noting that "[t]he overwhelming majority of courts which have considered whether brand manufacturers could be held liable for harms caused by their generic counterparts have answered in the negative." Although Judge Murphy went on to reconsider the logical basis for this conclusion in light of Mensing, the Court is required to take the law and the judicial precedent as they presently exist.

Thus, having considered the relevant Sixth Circuit, Eighth Circuit and Kentucky case law, the Court determines that Plaintiffs cannot state a product liability claim (or a derivative claim) against the Brand Defendants when Ms. Neeley did not use Brand Defendants' product, Reglan. The Court grants the Brand Defendants' Motion for Summary Judgment because Plaintiffs cannot establish the Brand Defendants' product caused Plaintiffs' injury nor can Plaintiffs satisfy the duty element of their negligence claims. The Court declines to hold the Brand Defendants liable for the Generic Defendants' product. Furthermore, as in Smith, the Court declines to find liability based upon drug designer liability.

In sum, the Court agrees with the holding in Smith and grants summary judgment in favor of the Brand Defendants on Plaintiffs' claims for negligence, negligent misrepresentation and negligent supply of information for the guidance of others (Count I), breach of warranty (Count III), misrepresentation and fraud (Count VI), strict product liability (Count VIII), loss of consortium (Count XII), punitive damages (Count XIII), violation of the KCPA (Count IX), and Plaintiff's damages (Count XIV).[18]

Accordingly,

**IT IS HEREBY ORDERED** that Barr Laboratories, Inc.; Barr Pharmaceuticals, LLC; and Watson Laboratories, Inc.'s Motion to Dismiss [146] is **DENIED**.

**IT IS FURTHER ORDERED** that Wolters Kluwer Health, Inc. and Wolters Kluwer United States, Inc.'s Motion to Dismiss [144], Barr Laboratories, Inc.; Barr Pharmaceuticals, LLC; Watson Laboratories, Inc.; Wolters Kluwer Health, Inc.; and Wolters Kluwer United States, Inc.'s Motion to Dismiss Based On Insufficient Allegations [148], Defendant Watson

[18] The Court also previously dismissed Plaintiffs' MMPA claim (Count IX), and the Court dismissed Plaintiffs' claim for joint and several liability, enterprise liability, market share liability, concert of action liability (Count X) as to all defendants, without prejudice.

Pharma, Inc.'s Notice of Joinder in Barr Laboratories, Inc.; Barr Pharmaceuticals, LLC; Watson Laboratories, Inc.; Wolters Kluwer Health, Inc.; and Wolters Kluwer United States, Inc.'s Motion to Dismiss Based On Insufficient Allegations [167] are **DENIED**, in part, and **GRANTED**, in part. Plaintiffs' MMPA claim in Count IX is **DISMISSED** and Count X is **DISMISSED** without prejudice.

**IT IS FINALLY ORDERED** that Defendant Wyeth LLC, Wyeth Pharmaceuticals Inc., and Schwartz Pharma, Inc. n/k/a UCB, Inc.'s Motion for Summary Judgment [174] is **GRANTED**, in part.[19]

Dated this 30th day of July, 2013.

**JOHN A. ROSS**
**UNITED STATES DISTRICT JUDGE**

[19] The Court notes that it dismissed Count X, without prejudice, as to all defendants, including Brand Defendants.